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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,680	01/25/2002	Teddy Kosoglou	CV01492K	9993

24265 7590 02/23/2005

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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/23/2005

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/056,680
Filing Date: January 25, 2002
Appellant(s): KOSOGLOU ET AL.

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For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 5, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1, 3, 11, 18-20, 35-37, 42-45, and 47 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

EP 0720 599	Rosenblum et al.	5-1997
WO99/47123	Ullah	9-1999

Frei., Proc Soc Exp Biol Med. 1999 Dec; 222(3): 196-204

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3, 11,18-20, 35-37, 42-45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum et al. (EP 0720 599, reference CA from IDS received January 21, 2003), and Ullah (WO 99/47123 from IDS received January 21, 2003) in view of Frei (Proc Soc Exp Biol Med. 1999 Dec; 222(3): 196-204).

Rosenblum et al. teaches a composition comprising the compound of Formula (II), lactose, and magnesium stearate (See particularly claims 8, and 9, page 24, example 6, page 29, Examples A and B). Rosenblum et al. also teaches the active compounds therein, including the racemic mixture of compound of Formula (II), can be formulated into a tablet (See Example A and B in page 29). Rosenblum et al. also teaches the effective dosage of compound of Formula (II) as 5 to 1000mg per day (See page 17, paragraph 0065). Rosenblum et al. also teaches the active compounds therein can be combined with HMG-CoA reductase inhibitors, preferably simvastatin, for reducing cholesterol and the risk of artherosclerosis (See 5, paragraph 0028, also claims 16 and 17).

Ullah teaches a composition comprising statins, such as simvastatin, in combination with aspirin, for cholesterol lowering and treating or reducing the risk of

developing atherosclerosis (See the abstract, also page 1, lines 14-18). Ullah teaches the dosage for aspirin as 50-650mg (See page 5, lines 34-37).

The primary references do not expressly teach the composition comprising the compound of formula (II) herein, aspirin, and simvastatin together. The primary references do not expressly teach antioxidants be incorporated into the composition containing compound of formula (II) herein, aspirin, and simvastatin.

Frei teaches antioxidants, such as vitamin C and vitamin E, as useful in inhibit the atherogensis and normalize the vascular functions (See the abstract, page 198, col. 2, second paragraph, also page 199, col. 1, second paragraph, page 201, col. 2, first paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the compound of Rosenblum into the composition of Ullah. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an antioxidant into the composition containing compound of formula (II) herein, aspirin, and simvastatin.

One of ordinary skill in the art would have been motivated to combine the compound of Rosenblum into the composition of Ullah. Combining composition of Rosenblum and that of Ullah, which are known to be useful to reduce cholesterol level and the risk of atherosclerosis individually, into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

One of ordinary skill in the art would have been motivated to incorporate an antioxidant into the composition containing the compounds of formula (II) herein,

aspirin, and simvastatin. Vitamin C, an antioxidant, is known as useful to inhibit the development of atherosclerosis. Therefore, combining vitamin C with composition containing compounds of Rosenblum and Ullah, which are known to be useful to reduce cholesterol level and the risk of atherosclerosis individually, into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

(11) Response to Argument

Appellant's arguments in page 6 of the Brief averring the cited prior art's failure to provide motivation to combine the teachings of the cited prior arts are not convincing. Examiner notes that the basis of the rejection is the fact that the herein claimed agents (i.e., the composition of Rosenblum et al., Ullah and Frei) are well-known to be useful for reducing the risk of atherosclerosis individually. Therefore, absent evidence to the contrary, it flows logically to combine these agents together, in different mix-and-match manner, in order to formulate a single composition useful for the very same purpose (See *In re Kerkhoven* 205 USPQ 1069). Such composition would at least expect additive effects in reducing the risk of atherosclerosis.

Appellant also argues unconvincingly in page 6, second part of page 6 that Ullah does not disclosed a combination of a sterol inhibitor and aspirin. Examiner notes that the outstanding rejection is an obviousness rejection and Ullah is only one of the three cited prior arts. Therefore, Ullah alone would not be teaching such combination. In any ways, the basis of the rejection is that the compositions of Rosenblum et al., Ullah, and Frei are known to be useful in inhibiting atherosclerosis. Therefore, one of ordinary skill

in the art would have been motivated to combine these agents together in a single composition useful for the very same purpose (See *Kerkhoven supra*).

Appellant's arguments in bottom of page 6 bridging to page 7 averring the cited prior art's failure to provide motivation to combine because the herein claimed agents having different mechanism of actions such as lowering cholesterol for the statins and sterol inhibitors, and reducing myocardial infarction for aspirin are unconvincing. The basis of the outstanding rejection is that the herein claimed agents are known to be useful for reducing the risk of atherosclerosis. The motivation to combine presented in the previous office action is not because of their mechanism of actions. Absent evidence to the contrary, it flows logically to combine these agents into a single composition useful for the very same purpose, at least additive effect would be expected.

Appellant's arguments in pages 7-9 are essentially the same as that presented in pages 6-7. Appellant's arguments in pages 7-8 of the Brief averring the cited prior art's failure to provide motivation to combine the teachings of the cited prior arts are not convincing. Examiner notes that the basis of the rejection is the fact that the herein claimed agents (i.e., the composition of Rosenblum et al., Ullah and Frei) are well-known to be useful for reducing the risk of atherosclerosis individually. Therefore, absent evidence to the contrary, it flows logically to combine these agents together, in different mix-and-match manner, in order to formulate a single composition useful for the very same purpose (See *In re Kerkhoven* 205 USPQ 1069). Such composition would at least expect additive effects in reducing the risk of atherosclerosis.

Appellant's arguments in bottom of page 8 bridging to page 9 averring the cited prior art's failure to provide motivation to combine because the herein claimed agents having different mechanism of actions such as lowering cholesterol for the statins and sterol inhibitors, and reducing myocardial infarction for aspirin are unconvincing. The basis of the outstanding rejection is that the herein claimed agents are known to be useful for reducing the risk of atherosclerosis. The motivation to combine presented in the previous office action is not because of their mechanism of actions. Absent evidence to the contrary, it flows logically to combine these agents into a single composition useful for the very same purpose, at least additive effect would be expected.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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February 18, 2005

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